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In re Application of :
Brockhaus et al :
Serial No.: 08/444,791 :Decision on Petition
Filed : 19 May 1995 :
Attorney Docket No.: 01017/40451C :

This letter is in response to the Petition under 37 C.F.R. 1.181 filed on 14 May 2007 requesting withdrawal of the restriction requirement and the finality of the Office action mailed 12 March 2007. The delay in acting upon this petition is regretted.

BACKGROUND

In brief, this application was filed on 19 May 1995 as a Rule 60 divisional of 08/095,640 which was filed on 21 July 1993 and claims priority to 07/862,495, filed 2 April 1992.

On 11 March 1993, the examiner set forth a restriction requirement along with documenting a telephonic election by applicants for prosecution of Group I:

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-29 and 36-46, drawn to recombinant vectors and DNA encoding the soluble TNF receptor and IgG, classified in Class 536, subclass 27.

II. Claims 30-35, drawn to the chimeric TNF receptor and IgG protein, classified in Class 530, subclass 387.3.

III. Claims 47 and 48, drawn to a method for producing antibodies to the chimeric protein, classified in Class 435, subclass 69.6.

IV. Claims 49-53, drawn to a method of assaying a ligand for the chimeric protein, classified in Class 435, subclass 7.1.

V. Claims 54-56, drawn to a method of disrupting the normal physiology of cytokine-secreting tumors, classified in Class 424, subclass 85.1.

On 11 March 1993, the examiner then examined Group I, claims 1-29 and 36-46, directed to recombinant vectors and DNA encoding the a chimeric protein comprising soluble TNF receptor and immunoglobulin. Claims 41-46, as filed 2 April 1992, were directed to the method of producing a chimeric polypeptide by producing a recombinant host cell and culturing the host cell under appropriate conditions to express and recover the polypeptide. Thus Group I, as originally examined, was directed to recombinant vectors and DNA encoding a chimeric protein comprising the soluble TNF receptor and immunoglobulin and the method of producing a chimeric polypeptide by producing a recombinant host cell and culturing the host cell under appropriate conditions to express and recover the polypeptide.

On 1 October 1993, the examiner prepared a non-final Office action in which claims 1-29 and 36-46 were rejected.

On 3 January 1994, the examiner prepared a Notice of Allowance for claims 1-4, 6-16, 18-25, 27-29 and 36-46.

The Notice of Allowance was withdrawn on 4 May 1994 and claims 1-4, 6-16, 18-25, 27-29 and 36-46 were rejected over a newly issued patent. Claim 1, as amended on 17 February 1994, was examined on the merits. Claim 1 was generic to any extracellular portion of any cytokine page 6 of the specification (second full paragraph) discloses two truncated receptor molecules lacking transmembrane or cytoplasmic domains of 55 kD and 75 kD. Thus, the extracellular portion of

claim 1, as disclosed in the specification encompassed both the 55kd and 75kd portions of the TNF binding protein.

On 1 November 1994, a second Notice of Allowance was prepared for claims of Group I, which then issued on 21 July 1993 as US Patent Number 5,610,279.

On 19 May 1995 applicants filed a Rule 60 divisional of 08/095,640 and was given serial number 08/444,791.

On 12 February 1996, an examiner prepared a non-final action on the merits for claims 44-61, filed in preliminary amendment filed 19 May 1995. Claims 44-61 were directed to Group I. It is noted that Claim 52 was directed to a polynucleotide of claim 48, where said human immunoglobulin is selected from the group IgG, IgM, IgA or IgE. Claims 54 and 55, respectively, were directed to IgG1 and IgG3.

The application was then transferred to another examiner who set forth three separate requirements for restriction on 1 June 2001, 23 September 2003 and 25 January 2006.

On 1 June 2001, the examiner required a first election of species between
DNA encoding 55kd TNFBP and
DNA encoding 75kd TNFBP

On 1 June 2001, the examiner required a second election of species between
DNA encoding IgG1 and
DNA encoding IgG3.

On 23 September 2003, the examiner required an election of species between DNA encoding IgG, IgA, IgM or IgE. If applicants elected IgG, then an election of species was further required between IgG1 and IgG3. The examiner also required a restriction between DNA, protein and method of making protein from DNA.

On 25 January 2006, the examiner required a restriction between DNA, protein and method of making protein from DNA. The examiner required an election of species among polynucleotide encoding SEQ ID Nos 8, 10 or 12 or any combination thereof. It is noted that SEQ ID Nos 8, 10 and 12 are all partial fragments of the amino acid sequence of 75kd TNFR.

On 12 March 2007, the examiner issued a Final Office action on the merits.

On 14 May 2007, applicants filed this petition to request that the Office reconsider the restriction requirement and the finality of the Office action mailed 12 March 2007.

DISCUSSION

The petition and file history have been carefully considered.

MPEP 803 states

I. CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent or distinct as claimed ; and

(B) There would be a serious burden on the examiner if restriction is not required.

The invention of original Group I was examined on the merits on 11 March 1993, 1 October 1993 and 4 May 1994, 1 November 1994 and 12 February 1996, prior to the three election of species and restriction requirements forth on 1 June 2001, 23 September 2003 and 25 January 2006. Given the extensive prosecution history, the Office cannot establish a showing of serious burden for further restriction or election of species requirement within this one particular invention. Further restriction among Group I was not warranted.

Moreover, the requirement for an election of species among polynucleotide encoding SEQ ID Nos 8, 10 or 12 or any combination thereof, is not warranted.

MPEP 806.03 states:

> Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.

MPEP 806.04(f) states:

> Where two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope.

The claim directed to the polynucleotide encoding SEQ ID Nos 8, 10 or 12 or any combination thereof is drafted in open claim language. All three species read upon the same embodiment, a polynucleotide that encodes the amino acid sequence of 75 kd TNFR.

MPEP 806 states:

> (C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper.

The election of species requirement among polynucleotides encoding SEQ ID Nos 8, 10 and 12 is not proper.

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above.

The original restriction requirement to the originally claimed groups, as set forth below, is maintained.

> **Restriction to one of the following inventions is required under 35 U.S.C. § 121:**
>
> **I. Claims 1-29 and 36-46, drawn to recombinant vectors and DNA encoding the soluble TNF receptor and IgG, classified in Class 536, subclass 27.**
>
> **II. Claims 30-35, drawn to the chimeric TNF receptor and IgG protein, classified in Class 530, subclass 387.3.**
>
> **III. Claims 47 and 48, drawn to a method for producing antibodies to the chimeric protein, classified in Class 435, subclass 69.6.**
>
> **IV. Claims 49-53, drawn to a method of assaying a ligand for the chimeric protein, classified in Class 435, subclass 7.1.**
>
> **V. Claims 54-56, drawn to a method of disrupting the normal physiology of cytokine-secreting tumors, classified in Class 424, subclass 85.1.**

In particular, the original restriction requirement between Group I, polynucleotides, and Group II, polypeptide, is maintained.

The restriction requirements mailed 1 June 2001, 23 September 2003 and 25 January 2006 have been withdrawn.

The restriction requirement between polynucleotide and method of using the polynucleotide to produce the polypeptide has been withdrawn.

The requirement to elect a single immunoglobulin species is withdrawn.

The requirement to elect a single IgG species is withdrawn.

The requirement to elect either the 55kd or 75 kd TNF BP is withdrawn.

The finality of the Office action mailed 12 March 2007 has been withdrawn.

The application will be forwarded to the examiner for further action consistent with this decision.

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions about this decision, please contact Special Program Examiner Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

John LeGuyader
Director, Technology Center 1600